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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/724,273

11/24/2003

Peter Palese

6923-119

4596

20583

7590

05/31/2007

JONES DAY

222 EAST 41ST ST

NEW YORK, NY 10017

EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

. 1648

MAIL DATE

DELIVERY MODE

05/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/724,273

Applicant(s)

PALESE ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-42,44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,9-11,15,18-20,26-30,32-36 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-42,44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply...</u> |

Serial No.: 10/724,273
Applicants: Palese, P., et al.

Docket No.: 6923-119
Filing Date: 11/24/2003

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 05 March, 2007. Claims 1-3, 9-11, 15, 18-20, 26-30, 32-36, 38-42, 44, and 45 are pending in the instant application. Applicants' election of Group VI (claims 40-42, 44, and 45) is acknowledged. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Claims 1-3, 9-11, 15, 18-20, 26-30, 32-36, 38, and 39 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 120

Applicants' priority claim under 35 U.S.C. § 120 is noted. Applicants are reminded that the first paragraph of the specification should be amended to reflect the status of all applications relied upon (i.e., U.S. Application No. 08/444,994 is now U.S. Patent No. 6,890,710 and U.S. Application No. 08/246,583 is now U.S. Patent No. 5,750,394).

37 C.F.R. § 1.98

Applicants are reminded that the listing of references in the specification is not a proper information disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, applications, or other information submitted for consideration by the Office, and M.P.E.P. § 609.04(a),

subsection I. states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

37 C.F.R. § 1.821

Applicants are reminded that sequences appearing in the specification and/or **drawings** (e.g., see Figures 2, 3, and 7-12) must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-42, 44, and 45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter

that will be protected by the patent grant. The reference to NS1I-1 is vague and indefinite since the actual nucleotide sequence encoding this protein is not readily manifest. Moreover, the reference to NS1I-1 is also vague and indefinite since the abbreviation is not defined in the claim. The term "selectively hybridizes" is also vague and indefinite since it fails to set forth the salient hybridization parameters. The hybridization conditions can vary considerably in any given reaction. Several factors influence the hybridization rate including the ionic strength, base composition, destabilizing agents, duplex length, temperature, etc. (see Table 2.10.2 in Brown, 1993). Thus, without clearly setting forth the metes and bounds of the patent protection desired, one skilled in the art would not be able to determine if they were infringing on the claimed invention. Finally, the reference to a functional equivalent is also vague and indefinite since no reference functions are provided in the claim language. What constitutes a functional equivalent? Does it share a similar enzymatic activity (i.e., steroid dehydrogenase activity) or some other property? Appropriate correction is required (i.e., An isolated DNA sequence which encodes an influenza A virus NS1 interacting protein, designated NS1I-1, wherein said nucleic acid comprises SEQ ID No...).

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 23, 25, 43-46, and 48-52 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Rochester*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). The claims are directed toward a nucleic acid encoding NS1I-1, or a sequence that hybridizes to a complement thereof. The claims do not set forth any meaningful structural or functional limitations.

The crux of the statutory requirement governing written description is whether one skilled in the art, familiar with the practice of the art at the time of the filing date, could reasonably have found the later claimed invention in the specification as filed. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). *In re Wilder*, 736 F.2d 1516, 1520 222 U.S.P.Q. 349, 372 (Fed. Cir. 1984, cert. denied, 469 U.S. 1209 (1985)). *Texas Instruments, Inc. v. International Trade Comm'n*, 871 F.2d 1054, 1063, 10 U.S.P.Q.2d 1257, 1263 (Fed. Cir. 1989). Moreover, the courts have stated that the evaluation of written description is highly fact-specific, and that broadly articulated rules are inappropriate. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). *In re Driscoll*, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (C.C.P.A. 1977). It is also important to remember that the

true issue in question is not whether the specification enables one of ordinary skill in the art to make the later claimed invention, but whether or not the disclosure is sufficiently clear that those skilled in the art will conclude that the applicant made the invention having the specific claim limitations. *Martin v. Mayer*, 823 F.2d 500, 505, 3 U.S.P.Q.2d 1333, 1337 (Fed. Cir. 1987).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has **possession** of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the

product claimed from the disclosed process. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1996).

In the instant application, applicants are attempting to claim a genus of nucleic acids without setting forth any meaningful structural or functional information. The claims simply reference a DNA sequence designated NS1I-1, or a sequence that hybridizes to the complement thereof. However, the claims fail to set forth the nucleotide sequence of encoding this protein. The claims fail to set forth any significant functional criteria (i.e., steroid dehydrogenase activity). The disclosure only identifies a single human nucleotide sequence that bears some similarity to a porcine steroid dehydrogenase. The disclosure fails to provide any additional sequences or guidance. Therefore, the skilled artisan would reasonably conclude that applicants were not in possession of the full genus of nucleic acid sequences at the time of filing.

Scope of Enablement

Claims 40-42, 44, and 45 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As set forth *supra*, the claims are directed toward a nucleic acid encoding NS1I-1, or a sequence that hybridizes to a complement thereof. The claims do not set forth any meaningful structural or functional limitations.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129

(C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

Quantity of Experimentation

The disclosure only provides a single NS1I-1 nucleic acid sequence (see Figure 12). A yeast interactive trap system was employed to identify proteins that interact with the influenza A NS1 protein. However, this screening assay only identified a single protein that is capable of interacting with NS1. Thus, even if the skilled artisan repeated the procedure several times using various libraries, it is not readily manifest that any other proteins of interest would be detected.

Amount of Direction Provided

As set forth in the preceding paragraph, the claims encompass any NS1I-1 interacting protein without setting forth any meaningful structural or functional information. The disclosure fails to provide any other nucleotide sequences of any other human proteins that are capable of interacting with NS1 other than the one set forth in Figure 12.

Working Embodiments

The disclosure only provides a single working embodiment. No other interacting proteins are identified.

Unpredictability of the Prior Art

The prior art is clearly unpredictable as evidenced by the fact that applicants were only able to identify a single nucleic acid sequence using the yeast trap assay. Thus, the skilled artisan appears to have a limited chance at identifying any additional interacting proteins.

Therefore, when all the aforementioned factors are considered in toto, it would clearly require undue experimentation to practice the claimed invention.

Correspondence

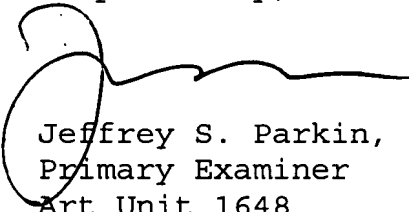
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and

Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

29 May, 2007

Notice to Comply

Application No.
10/724,273

Applicant(s)
Palese, P., et al.

Examiner
Jeffrey S. Parkin

Art Unit
1648

Paper No.
05/29/2007

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Applicants are reminded that sequences appearing in the specification and/or **drawings** must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification and drawings.

Applicant May Need to Provide:

- ☒ An substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
 - For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
 - Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov.
- To Download Patentin Software, visit <http://www.uspto.gov/web/patents/software.htm>.

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

1441 GTAGCCATACCTAATAGACCTCCTGATGCTGTACTTACAGATACCACCTCTCTTAATCAGGCTGCTTTGTACCGCCTCAG 1520
V A I P N R P P D A V L T D T T S L N Q A A L Y R L S 507

1521 TGGAGACCGGAATCCCTTACACATTGATCCTAACTTTGCTAGTCTAGCAGGTTTTGACAAGCCCATATTACATGGATTAT 1600
G D R N P L H I D P N F A S L A G F D K P I L H G L 533

1601 GTACATTTGGATTCTCTGCCAGGCGTGTGTACAGCAGTTTGCAGATAATGATGTGTCAAGATTCAAGGCAGTTAAGGCT 1680
C T F G F S A R R V L Q Q P A D N D V S R F K A V K A 560

1681 CGTTTTGCAAAACAGTATATCCAGGACAACTCTACAACTGAGATGTGGAAGGAAGGAAACAGAATTCATTTTCAAAC 1760
R F A K P V Y P G Q T L Q T E M W K E G N R I H F Q T 587

1761 CAAGGTCCAAGAACTGGAGACATTGTCAATTCAAATGCATATGTGGATCTTGCACCAACATCTGGTACTTCAGCTAAGA 1840
K V Q E T G D I V I S N A Y V D L A P T S G T S A K 613

1841 CACCCTCTGAGGGCGGGAAGCTTCAGAGTACCTTTGTATTGAGGAAATAGGACCGCCGCTAAAGGATATTGGGCCTGAG 1920
T P S E G G K L Q S T F V F E E I G R R L K D I G P E 640

1941 GTGGTGAAGAAAGTAAATGCTGTATTGAGTGGCATATAACCAAAGGCGGAATATTGGGGCTAAGTGGACTATTGACCT 2000
V V K K V N A V F E W H I T K G G N I G A K W T I D L 667

2001 GAAAAGTGGTTCTGGAAAAGTGTACCAAGGCCCTGCAAAAGGTGCTGCTGATACAACAATCATACTTTCAGATGAAGATT 2080
K S G S G K V Y Q G P A K G A A D T T I I L S D E D 693

2081 TCATGGAGGTGGTCTCTGGGCAAGCTTGACCCTCAGAAGGCATTCTTTAGTGGCAGGCTGAAGGCCAGAGGGAACATCATG 2160
F M E V V L G K L D P Q K A F F S G R L K A R G N I M 720

2161 CTGAGCCAGAACTTCAGATGATTCTTAAAGACTACGCCAAGCTCTGAAGGGCACACTACACTATTAATAAAAATGGAAT 2240
L S Q K L Q M I L K D Y A K L 735

2241 CATTAAATACTCTCTTCACCCAAATATGCTTGATTATTCTGCAAAAGTGATTAGAACTAAGATGCAGGGGAAATTGCTTA 2320

2340 ACATTTTCAGATATCAGATAACTGCAGATTTTCATTTTCTACTAATTTTTCATGTATCATTATTTTACAAGGAACATA 2400

2401 TATAAGCTAGCACATAATTATCCTTCTGTTCTTAGATCTGTATCTTCATAATAAAAAATTTTGCCCAAGTCTGTTTCC 2480

2480 TTAGAATTTGTGATAGCATTGATAAGTTGAAAGGAAAATTAAATCAATAAGGCCTTTGATACCTTTAAAAA 2560
AAAAA

FIG. 12B